DAVID M. BERNICK (*pro hac vice*)
david.bernick@kirkland.com
PETER A. FARRELL (*pro hac vice*)
peter.farrell@kirkland.com
KIRKLAND & ELLIS LLP
1301 Pennsylvania Ave., N.W.
Washington, DC 20004
Telephone: (202) 389-5000
Facsimile: (202) 389-5200

RENEE D. SMITH (*pro hac vice*)
renee.smith@kirkland.com
KIRKLAND & ELLIS LLP
300 North LaSalle
Chicago, IL 60654
Telephone: (312) 862-2000
Facsimile: (312) 862-2200

GREGORY P. STONE (SBN 78329)
gregory.stone@mto.com
DANIEL B. LEVIN (SBN 226044)
daniel.levin@mto.com
BETHANY W. KRISTOVICH (SBN 241891)
bethany.kristovich@mto.com
MUNGER, TOLLES & OLSON LLP
350 South Grand Avenue, 50th Floor
Los Angeles, CA 90071-3426
Telephone: (213) 683-9100
Facsimile: (213) 687-3702

Attorneys for Defendant Juul Labs, Inc.

UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

IN RE: JUUL LABS, INC., MARKETING, SALES PRACTICES, AND PRODUCTS LIABILITY LITIGATION

This Document Relates to:

ALL ACTIONS

Case No. 19-md-02913-WHO

REPLY IN SUPPORT OF INTRODUCTORY "ROADMAP" TO DEFENDANT JUUL LABS, INC.'S OMNIBUS *DAUBERT* MOTIONS

Judge: Hon. William H. Orrick
Date: February 25, 2022
Time: TBD
Ctrm: 2

INTRODUCTION

Plaintiffs' Opposition does not shake the rigorous requirements of *Daubert* and Rule 702, which require that expert opinions be "scientifically valid," "supported by appropriate validation," and fit the facts of the case. *Daubert v. Merrell Dow Pharms., Inc.,* 509 U.S. 579, 590–93 (1993) (*"Daubert I"*); Fed. R. Evid. 702. Although Plaintiffs seek to downplay these requirements, they ultimately do not disagree (and their authorities demonstrate) that *Daubert* excludes opinions that are unreliable, speculative, or that are not relevant because they are not tied to the real-world facts facing the parties in the case. Nor do Plaintiffs dispute that *Daubert* is a critical juncture in MDL cases, serving to narrow the claims that may make it to a jury, weed out far-fetched causal theories, and at times even end massive MDL proceedings entirely. *See* JLI Roadmap at 5–8; *see also*, *e.g.*, *In re Phenylpropanolamine (PPA) Prods. Liab. Litig.*, 289 F. Supp. 2d 1230, 1243 (W.D. Wash. 2003).

This MDL is not different. As discussed in JLI's accompanying briefs, Plaintiffs' experts' opinions fall well short of *Daubert*'s requirements, failing to reliably grapple with the real-world facts of JLI's marketing activities, the science surrounding addiction and the health effects of JUUL products, or the regulatory framework that inevitably shaped JLI's actions. Each of the opinions identified in Appendix A should be excluded.

I. *Daubert* Requires That The Court Exercise Its Gatekeeping Function And Eliminate Unqualified, Unreliable, Or Irrelevant Opinions.

Plaintiffs do not dispute that the Court "cannot abdicate its role as gatekeeper," *Estate of Barabin v. AstenJohnson, Inc.*, 740 F.3d 457, 464 (9th Cir. 2014), and that opinions falling short of Rule 702's requirements are impermissible. To begin, Plaintiffs thus agree that witnesses must be qualified by "knowledge, skill, experience, training, or education" before offering expert opinions, Fed. R. Evid. 702, and that admissibility depends on whether the opinion falls "within the reasonable confines of [the witnesses'] subject area." Pls. Br. 23 (quoting *Avila v. Willits Env't Remediation Tr.*, 633 F.3d 828, 839 (9th Cir. 2011)). Indeed, the *Avila* case on which Plaintiffs rely affirmed a district court's decision excluding a chemist's opinions for precisely this reason. *Avila*, 633 F.3d at 839. Similarly, Plaintiffs do not dispute that expert opinions must be reliable—Plaintiffs recognize, as they must, that opinions are admissible only if they are "based on sufficient facts or data," are "the product of reliable principles and

methods," and "reliably appl[y] the principles and methods to the facts of the case." Pls. Br. 22 (quoting Fed. R. Evid. 702)). And although Plaintiffs emphasize that opinions may be "shaky but admissible," Pls. Br. 22, they do not dispute that opinions are not even "shaky"—but instead are flatly inadmissible—if "[a]ny step" in the analysis renders it without reliability. *In re Zoloft (Sertraline Hydrochloride) Prods. Liab. Litig.*, 858 F.3d 787, 800 (3d Cir. 2017); *see also Hardeman v. Monsanto Co.*, 997 F.3d 941, 962 (9th Cir. 2021) (criticizing "incorrect assumption that this court is more permissive than others in admitting *Daubert* testimony"). The problem for Plaintiffs is that many of their expert opinions—including all of the opinions identified in Appendix A—do not meet these standards.

Plaintiffs also do not dispute that expert opinions must "fit" the issues of the case, and "help the trier of fact to understand the evidence or to determine a fact in issue." Fed. R. Evid. 702(a). Opinions that are not "sufficiently tied to the facts of the case" are not relevant or helpful to the jury. *Daubert I*, 509 U.S. at 591. If opinions do not "speak[] clearly and directly to an issue in dispute in the case," they should be excluded. *Daubert v. Merrell Dow Pharms., Inc.*, 43 F.3d 1311, 1321 n.17 (9th. Cir. 1995) (*Daubert II*). As discussed in JLI's other briefs, that is a consistent problem with the opinions Plaintiffs' experts offer.

II. Plaintiffs' Experts Cannot Ignore the TCA And FDA Regulation.

The key requirement that opinions "fit" the facts of the case explains why Plaintiffs are wrong to argue that the Court should ignore the role of the TCA. In Plaintiffs' telling, the TCA, federal regulation, and federal preemption are all "untethered to the principles of . . . admissibility." Pls. Br. 25–28. But Plaintiffs are wrong to downplay the rules that actually governed JLI's choices in this matter. The TCA and federal regulation are relevant to the *Daubert* inquiry because reliable expert opinions that fit the facts of this case would necessarily consider the real-world constraints that JLI actually was required to act under, and because those opinions would also consider and respect the FDA's guidance on what is and is not "appropriate for the protection of the public health." 21 U.S.C. § 387f(d)(1). Opinions that completely ignore regulatory constraints or that are completely contradictory to FDA guidance do not fit the facts of the case and so should not be presented to the jury. *Daubert I*, 509 U.S. at 591.

This is not a theoretical problem or something that Plaintiffs can wish away in this case. Plaintiffs miss the point when they argue that there is no broad "field preemption" in the TCA, Pls. Br. 27; the more

immediate problem is that Plaintiffs' experts repeatedly and wrongly offer opinions on the reasonableness of JLI's choices as if the TCA never existed and as if the FDA had not made any determinations regarding ENDS at all. To take just one dramatic example, Plaintiffs' experts offer the opinion that JLI should have created only extremely-low-nicotine content products, *e.g.*, "1.7% or better yet 0% nicotine," Ex. 18, Prochaska Rep. 55, or products with cessation "feature[s] . . . that would allow users to taper themselves off nicotine at their own election." Ex. 23, Shihadeh Rep. 56. But these opinions ignore that the FDA "support[s] development of alternative tobacco products"—including tobacco products that contain nicotine—"with the potential to reduce harm." Deeming Tobacco Products to Be Subjected to the Federal Food, Drug, and Cosmetic Act, 81 Fed. Reg. 28973, at 29001 (May 10, 2016); *see also* 21 U.S.C. § 387g(d)(3)(B) (forbidding the FDA from "requiring the reduction of nicotine yields of a tobacco product to zero"). Indeed, cessation products are "new drugs" subject to an entirely different regulatory process. *See* 21 U.S.C. § 355 ("New drugs"). It would conflict with the "purposes and objectives" of the regulatory scheme Congress created if state law prohibited ENDS manufacturers from offering PMTA-authorized products and permitted only cessation products that require approval through a different federal regulatory scheme. *Cohen v. Apple Inc.*, 497 F. Supp. 3d 769, 773 (N.D. Cal. 2020). That would render the TCA—the most significant tobacco legislation in a generation—a dead letter. Yet under plaintiffs' experts' telling, even PMTA-authorized ENDS products that have positive nicotine content or enough nicotine to be potentially addictive (as would be expected of tobacco products appealing to adult smokers) would nevertheless violate and be subject to massive liability under state law.

Such opinions completely ignore the framework governing ENDS products and the real-world considerations of a company seeking to market an alternative to cigarettes and so neither fit the facts of this case nor are helpful to the jury. *See* JLI Br. #2. Nor are Plaintiffs' experts' opinions on other topics any better—as is discussed in JLI's separate briefs, Plaintiffs' experts repeatedly opine that JLI should have marketed, designed, and warned about its products in ways that are completely contrary to the regulatory framework that actually guided JLI's actions.[1] And although Plaintiffs may believe that this

[1] Plaintiffs' argument that "all of the design (and most of the marketing) decisions JLI made—that are at the heart of this case—were made *pre-deeming*, and thus the TCA did not even apply to JLI's product," Pls. Br. 28, is misplaced and adverse to the record. Plaintiffs cannot avoid that the TCA had been enacted

problem "goes to the weight of the . . . testimony, not its admissibility," Pls. Br. 29, that doctrine is no panacea for opinions that are completely disconnected from considerations guiding the parties before the Court. Opinions that do not fit the facts of the case are not simply flawed—they are inadmissible and should be excluded. *Daubert II*, 43 F.3d at 1321 n.17.

Dated: February 14, 2022

Respectfully submitted,

By: */s/ Renee D. Smith*
Renee D. Smith (*pro hac vice*)
KIRKLAND & ELLIS LLP
300 N. LaSalle
Chicago, IL 60654
Telephone: (312) 862-2310

By: */s/ David Bernick*
David Bernick (*pro hac vice*)
Peter A. Farrell (*pro hac vice*)
KIRKLAND & ELLIS LLP
1301 Pennsylvania Ave, N.W.
Washington D.C. 2004
Telephone: (202) 389-5959

Attorneys for Defendant Juul Labs, Inc.

by the time JLI was designing its products, and JLI viewed balancing public health considerations as "a north star for a decade or more." Ex. 63 Cohen Dep. 854:7–18.

CERTIFICATE OF SERVICE

I hereby certify that on February 14, 2022, I electronically filed the foregoing document with the Clerk of the Court using the CM/ECF system, which will automatically send notification of the filing to all counsel of record. I also caused a copy of the under-seal documents to be served via electronic mail on all parties.

By: */s/ Renee D. Smith*

Renee D. Smith